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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/030,271	06/28/2002	Toshio Ota	217860US	9016

22850 7590 06/07/2005

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1940 DUKE STREET
ALEXANDRIA, VA 22314

EXAMINER	
YAO, LEI	

ART UNIT	PAPER NUMBER
1642	

DATE MAILED: 06/07/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/030,271	OTA ET AL.	
	Examiner	Art Unit	
	Lei Yao, Ph.D.	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 May 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-52* is/are pending in the application.

4a) Of the above claim(s) *9,14-19,21-24 and 42-52* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *1-8,10-13,20 and 25-41* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *2/4/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: *Exhibit A and B*.

DETAILED ACTION

Election/Restrictions

Applicant's election of Group I (claims 1-8, 10-13, 20, and 25-41) in the reply filed on 5/11/2005 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 1-52 are pending. Claims 9,14-19,21-24 and 42-52 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Claims 1-8,10-13,20 and 25-41 are examined on the merits.

Priority

An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence(s) of the specification or in an application data sheet by identifying the prior application by application number (37 CFR 1.78(a)(2) and (a)(5)). If the prior application is a non-provisional application, the specific reference must also include the relationship (i.e., continuation, divisional, or continuation-in-part) between the applications except when the reference is to a prior application of a CPA assigned the same application number.

Claim Objections

Claim 5 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 5 is drawn to a nucleotide encoding a partial peptide of the base claim 1. In order to be a proper dependent claim, the dependent claim should include all the limitation of its base claim. The partial sequence of claim 5 does not include all the limitation of the base claim.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-8 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The products, polynucleotides of SEQ ID NO: 1 and 3, encoding proteins having apoptosis-inducing activity exist in nature, which do not constitute patentable subject matter as defined in 35 U.S.C. 101. The claimed inventions do not show involvement of the "hand of man". Amending the claims to require that polynucleotides of SEQ ID NO: 1 and 3 are purified or isolated would indicate the "hand of Man".

Claim Rejections - 35 USC § 112

The following is a quotation of the **second paragraph** of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 3, and 7- 8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 (d) and 3 (h) recite "stringent conditions", but it is not clear what the metes and bounds are. The specification at page 12, line 20-32 teach that examples of "stringent conditions". However, the specification does not define what "stringent conditions" are. Therefore, Claims 1 (d) and 3 (h) are indefinite.

Claims 7 and 8 are construed with a preamble" a polynucleotide" and a transitional phrase "comprising" and the body of the claim, which appear to be "SEQ ID NO: 4". The claim as currently drafted is confusing as to whether the scope include "polynucleotide encoding a protein that comprise the amino acid sequence of SEQ ID NO: 4 or excludes it. The scope of the open transitional phrase "comprising" includes the unrecited parts and/or component.

Claim 8 is confusing as to the scope of the property landing. It is not clear the claim limitation of changing amino acid at position 300-303. It could mean changing 1) only one position, 2) all four positions, 3) any position between, or 4) all above. After consulting the entire specification, it is still not clear what is encompassed by the limitation.

The following is a quotation of the **first paragraph** of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Drawn to Written Description

Claims 1-7, 10-13, 20 and 25-41 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

> The applicable standard for the written description requirement can be found: MPEP 2163; University of California v. Eli Lilly, 43 USPQ2d 1398 at 1407; PTO Written Description Guidelines; Enzo Biochem Inc. v. Gen-Prove Inc., 63 USPQ2d 1609; Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111; and University of Rochester v. G.D. Searle & Co., 69 USPQ2d 1886 (CA FC 2004).

Claims 1-7, 10-13, 20 and 25-41 are drawn to genus of polynucleotides because of the limitation of "a polynucleotide encoding a protein comprising an amino acid sequence of SEQ ID NO: 2 or 4 with one or more amino acid are substituted, deleted, inserted, and/or added", "a polynucleotide hybridizing under stringent condition with a polynucleotide comprising the nucleotide sequence of SEQ ID NO: 1 or 3", "polynucleotide having 60% or more homology to the nucleotide sequence of SEQ ID NO:1 or 3, and "a polynucleotide encoding molecular-evolutionarily the same gene as a gene comprising the nucleotide sequence of SEQ ID NO: 3".

The specification discloses polynucleotides of a nucleotide sequence of SEQ ID NO: 1 and 3. The specification does not disclose representative number of species. The instant claims encompass

significant structural dissimilarity as compared to the polynucleotides of SEQ ID NO: 1 or 3. SEQ ID NO: 1 and 3 do not represent claimed genus because the genus includes molecules which differ widely in structural attributes from nucleotide sequence of SEQ ID NO: 1 or 3. Thus, one skill in the art cannot envision the detailed chemical structure of claimed genus.

To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof. In this case, the only factor present in claims is the function characteristic, i.e. "apoptosis-inducing activity" with the broadly drafted partial structures of "a polynucleotide encoding a protein comprising an amino acid sequence of SEQ ID NO: 2 or 4 with one or more amino acid are substituted, deleted, inserted, and/or added", "a polynucleotide hybridizing under stringent condition with a polynucleotide comprising the nucleotide sequence of SEQ ID NO: 1 or 3", "a polynucleotide having 60% or more homology to the nucleotide sequence of SEQ ID NO:1 or 3, and "a polynucleotide encoding molecular-evolutionarily the same gene as a gene comprising the nucleotide sequence of SEQ ID NO: 3". No identification of any particular portion of the structure as polynucleotide of SEQ ID NO: 1 or 3 are conserved in the claimed genus in order to have the recited function of apoptosis-inducing activity. The instant specification does not provide a specific or detail structural characteristics of the fragments, variants or the derivatives of polynucleotide of SEQ ID NO: 1 or 3. In addition, claim 1 (d) currently construes that a polynucleotide hybridizes to the human coding sequence, i.e. SEQ ID: 1 also encoded a protein having apoptosis-inducing activity. Vanhee-Brossollet et al., teach that naturally occurred antisense, i.e. a nucleic acid strand hybridizes to a nucleic acid coding strand. However, the antisense does not appear to code any protein. The function of the antisense is to govern the expression of their sense cording part (abstract). In the absence of any evidence to the contrary to what is known in the art about the antisense, the office conclude that the specification fail to provide an adequate description of the correlation between the functional language of " apoptosis-inducing activity and the partial structure draft in claim in claim 1(d).

Accordingly, in the absence of sufficient recitation of distinguishing structural and functional characteristics, the specification does not provide adequate written description of the claimed genus. Therefore, the written description is not commensurate in scope with the claims, which read on "a polynucleotide encoding a protein comprising an amino acid sequence of SEQ ID NO: 2 or 4 with one or more amino acid are substituted, deleted, inserted, and/or added", "a polynucleotide hybridizing under stringent condition with a polynucleotide comprising the nucleotide sequence of SEQ ID NO: 1 or 3", "polynucleotide having 60% or more homology to the nucleotide sequence of SEQ ID NO: 1 or 3, and "a polynucleotide encoding molecular-evolutionarily the same gene as a gene comprising the nucleotide sequence of SEQ ID NO: 3". One of skill in the art would reasonably conclude that applicant is not in possession of the claimed genus.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, whatever is now claimed." (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116). As discussed above, the skilled artisan cannot envision the detailed chemical structure of the encompassed genus. Therefore, only polynucleotide comprising SEQ ID NO: 1 and 3, but not the full breadth of the claims meets the written description provision of 35 U.S.C. §112, first paragraph.

Drawn to Enablement of Transformant

Claims 11 and 29-33 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for making and using an transformant comprising the vectors of claims 10, or 25-28, do not reasonably provide enablement for any host cell comprising the vector of claims 10, and 25-28,. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

Claims 11 and 29-33 are drawn to a host cell comprising the vector of claims 10 or 25-28, respectively. The claims are broadly interpreted to encompass host cells, which are not isolated and are comprised within an organism. Thus, the claims encompass host cells that have been transfected with the vector of claims 10 or 25-28 that could be comprised within a transgenic animal, including nonhuman or human animals and animals treated using gene therapy.

The teachings of the specification cannot be extrapolated to the enablement of the claimed invention because the amount of guidance, direction, and exemplification set forth therein would not be sufficient to enable the skilled artisan to have a reasonable expectation of success in making and using the claimed invention without the need to perform additional, and an undue amount of experimentation. Factors to be considered in determining whether undue experimentation is required are summarized in *Ex parte Forman*, 230 USPQ 546 (BPAI 1986). These factors include the nature of the invention, the state of the prior art, the relative skill of those in the art, the amount of direction or guidance disclosed in the specification, the presence or absence of working examples, the predictability or unpredictability of the art, the breadth of the claims, and the quantity of experimentation which would be required in order to practice the invention as claimed.

The specification discloses construction of a vector therein can be introduced into mammalian cells (page 27, example 1). The specification does not provide a sufficient amount of guidance, direction, or exemplification to enable the skilled artisan to make or use host cells that are comprised within a non-human transgenic animal. In the art of producing transgenic animals, the phenotype of the resultant transgenic animal is not always predicable or viable. Houdebine (*Journal of Biotechnology* 1994, 34: 269-287) teaches the vectors to be used for directing the expression of transgenes in any given tissue, or in all tissues, must contain the appropriate regulatory regions. Houdebine teaches expression is heavily dependent on the site of integration in the host genome and the site of integration is presently unpredictable. Therefore, it is concluded that one of skill in the art would need to perform undue experimentation in order to make and use the claimed host comprised within a transgenic animal. In addition, the specification does not teach provide a sufficient amount of guidance, direction, and exemplification to enable the skilled artisan to have a reasonable expectation of successfully producing

transformant within a living organism, which comprise the vectors of claims 10 or 25-28, by gene transfer, or *gene therapy*. The art of gene therapy, i.e., the *in vivo* delivery genetic information to targeted cells within a body using naked DNA or viral vectors or by reintroducing *ex vivo* modified host cells into the body, is still in its infancy. Moreover, the art is highly unpredictable and its successful application has been hindered by numerous limitations, which the specification does not remedy and would preclude the skilled artisan from having a reasonable expectation of successfully making and using the claimed invention without need of performing an undue amount of experimentation. For example, the teachings of the specification have not overcome the problems with *in vivo* delivery and expression. Verma et al. (*Nature* 1997, 389: 239-242) teach that the Achilles heel of gene therapy is gene delivery. Verma et al. state that the ongoing problem is the inability to deliver genes efficiently and to obtain sustained expression. Similarly, Amalfitano et al. (*Current Gene Therapy* 2002, 2: 111-133) teach that non-viral mediated transfer of DNA generally suffers from low transduction efficiencies. In addition, Amalfitano et al. discuss numerous limitations that have been encountered in using retroviral vectors to deliver DNA into a subject and teach the use of adenoviral vectors can be ineffective because of the induction of strong immune responses in the host to the viral vectors and direct acute and chronic toxicity caused by the vector itself.

It is noted that Amalfitano et al. teach that a despite general lack of success, the first conclusive evidence that gene therapy can show efficacy in humans was achieved in human X-linked SCID subjects *via* retrovirus transduction. However, since the publication, The Department of Health and Human Services has released a memorandum dated January 14, 2003, a copy of which is attached to this Office action, that urges all such investigations to be discontinued until new data are available, the possible etiology and risks of adverse events associated are considered, and recommendations emerge. Despite the initial promise of the trial studying gene transfer as a possible treatment for the disease, investigators have found that retroviral-mediated insertion of the transgene has caused the subjects to develop cancer. The results of the trial underscore the high degree of unpredictability associated with the art and the fact that the skilled artisan could not make or use the claimed invention with a reasonable expectation of success without need to perform additional experimentation.

The state of the art, as a whole, is well defined by Pandha et al. (*Current Opinion in Investigational Drugs* 2000; 1 (1): 122-134) in the abstract. Pandha et al. teach:

> Despite the rapid technological advances that continue to sustain the field of cancer gene therapy, few individual patients have benefited from the revolution so far. The plethora of clinical trials described confirms that each malignancy will have its own ideal strategy based on the associated molecular defects, and there has been rapid progress from this viewpoint. At the same time, there has been a renewed appreciation for the limitations to gene therapy, which include low efficiency of gene transfer, poor specificity of response and methods to accurately evaluate responses, and lack of truly tumor-specific targets at which to aim. As with all new therapies, we are climbing a steep learning curve in terms of encountering treatment-related toxicities, as well as profound ethical and regulatory issues.

In view of the preponderance of evidence establishing the state of the art, now and at the time the application was filed, and the level of unpredictability associated therewith, in the absence of a disclosure of an amount of guidance, direction, and exemplification that is reasonably commensurate in scope with the claims, it appears that skilled artisan could not make and use the claimed invention with a reasonable expectation of success without having the need to perform an undue amount of experimentation. Amending claims 11 and 29-33 to recite "isolated" before "transformant" would obviate these grounds of rejection.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1(c), 3 (g), 5, and 7 are rejected under 35 U.S.C. 102(b) as being anticipated by Zoltan et al., (Cell, Vol 74, page 609-619, 1993).

Claims 1 (a) and 3 (a) are drawn to a polynucleotide encoding a protein or a precursor having apoptosis-inducing activity and the proteins in which one or more amino acid are substituted, deleted, inserted, and/or added. Claim 5 is drawn to a polynucleotide encoding a partial peptide of the protein. The claim 7 is drawn to a polynucleotide of claim 3(g), which has a character dominant negative to a protein comprising the amino acid sequence of SEQ ID NO: 4.

Zoltan et al., disclose that a polynucleotide encoding a protein, Bax, having apoptosis-inducing activity (page 611, figure 2 and abstract). Since the instant claims do not specify the upper limit of the number of amino acids being changed the claims read on the nucleic acid sequence encoding a protein having apoptosis-inducing activity (figure 2, page 611).

As for whether the protein encoded by the nucleic acid shown in Figure 2 of the prior art being dominant negative. The office does not have the facilities and resources to provide the factual evidence needed in order to establish that the product of the prior art does not possess the same material, structural and functional characteristics of the claimed product. In the absence of evidence to the contrary, the burden is on the applicant to prove that the claimed product is different from those taught by the prior art and to establish patentable differences. See In re Best 562F.2d 1252, 195 USPQ 430 (CCPA 1977) and Ex parte Gray 10 USPQ 2d 1922 (PTO Bd. Pat. App. & Int. 1989).

Claims 1-8, 10-13, 20, and 25-41 are rejected under 35 U.S.C. 102(e) as being anticipated by Ni et al., (US Patent Application Publication NO: US 2003/0049723, effective US filing date: 3/24/1999).

Claims 1 and 3 are drawn to a polynucleotide encoding a protein having apoptosis-inducing activity, said polynucleotide encoding a protein comprising the amino acid sequence of SEQ ID NO: 2 or 4, in which one or more amino acids are substituted: deleted, inserted, and/or added and said polynucleotide hybridizing under stringent condition with a polynucleotide comprising the nucleotide sequence of SEQ ID NONO: 1 or 3. Claims 2, 4-5 embody the claim 1 or 3, wherein the polynucleotide

having 60% homology or SEQ ID NO: 1 or 3 and partial peptide of a protein. Claims 6-7 embody the claim 3, wherein the polynucleotide encoding molecular-evolutionary the same gene as a gene comprising the DNA of SEQ ID NO: 3 or encoding a protein having substituted deleted, inserted, and/or added that has a character dominant negative to that of a protein comprising the amino acid sequence of SEQ ID NO: 4. Claims 10-13, 20, 25-37 -41 are drawn to a vector, transformant, a method for producing the proteins.

Ni et al., disclose apoptosis related polynucleotide (SEQ ID NO: 2, page 104), which is 99.8% identical to the sequence of SEQ ID NO: 1 as evidenced by sequence search (exhibit A) and 94% identical to the sequence of SEQ ID NO: 3 as evidenced by sequence search (exhibit B). Ni et al., further disclose that transformant containing host cell, vector, and DNA, and a method of protein production (sections 223-236, pages 29-30). Ni, et al., also disclose that polynucleotide which hybridizes to the complement of those nucleotide molecule under stringent hybridization condition (section 194-195, page 25). Ni, et al., further disclose polynucleotide complementary being at least 15 base pair, e.g., 15-25 base pair (section 379, page 47). Ni, et al., again disclose polynucleotide (DNA or RNA) complementary being 20-40 bases in length (section 398, page 49).

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lei Yao, Ph.D. whose telephone number is 571-272-3112. The examiner can normally be reached on 8am-4.30pm Monday to Friday.

Any inquiry of a general nature, matching or file papers or relating to the status of this application or proceeding should be directed to Kim Dowining for Art Unit 1642 whose telephone number is 571-272-0521

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Lei Yao, Ph.D.
Examiner
Art Unit 1642

LY

MISOOK YU
PATENT EXAMINER

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Db        691 CGGGTTCGAGCAGAGTACTGCGAGCATGGGCCAGCCTTGGAGCAGGGCGTGGCATCCCGG 750

Qy        661 CGGCCCCAGGCGCTGGCGCGGCAGCTGGACGTGTTTGGGCAGGCCACCGCAGTGCTGCGC 720
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        751 CGGCCCCAGGCGCTGGCGCGGCAGCTGGACGTGTTTGGGCAGGCCACCGCAGTGCTGCGC 810

Qy        721 TCAAGGGACCTGGGCTCTGTGGTTTGTGACATCAAGTTCTCAGAGCTCTCCTATCTGGAC 780
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        811 TCAAGGGACCTGGGCTCTGTGGTTTGTGACATCAAGTTCTCAGAGCTCTCCTATCTGGAC 870

Qy        781 GCCTTCTGGGGCGACTACCTGAGTGGCGCCCTGCTGCAGGCCCTGCGGGGCGTGTTCCTG 840
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
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Qy        841 ACTGAGGCCCTGCGAGAGGCTGTGGGCCGGGAGGCTGTTCGCCTGCTGGTCAGTGTGGAT 900
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
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Qy        901 GAGGCTGAC 909
              |||||||||
Db        991 GAGGCTGAC 999
```

RESULT 3
US-10-013-477-2
; Sequence 2, Application US/10013477
; Publication No. US20030049732A1
; GENERAL INFORMATION:
; APPLICANT: Ni et al.
; TITLE OF INVENTION: Apoptosis Related Polynucleotides, Polypeptides, and Antibodies
; FILE REFERENCE: PT002P1
; CURRENT APPLICATION NUMBER: US/10/013,477
; CURRENT FILING DATE: 2001-12-13
; PRIOR APPLICATION NUMBER: 09/669,445
; PRIOR FILING DATE: 2000-09-25
; PRIOR APPLICATION NUMBER: PCT/US00/06642
; PRIOR FILING DATE: 2000-03-15
; PRIOR APPLICATION NUMBER: 60/126,018
; PRIOR FILING DATE: 1999-03-24
; PRIOR APPLICATION NUMBER: 60/139,638
; PRIOR FILING DATE: 1999-06-17
; PRIOR APPLICATION NUMBER: 60/149,449
; PRIOR FILING DATE: 1999-08-18
; NUMBER OF SEQ ID NOS: 27
; SOFTWARE: PatentIn Ver. 2.0
; SEQ ID NO 2
; LENGTH: 2045
; TYPE: DNA
; ORGANISM: Homo sapiens
US-10-013-477-2

SeqID 11

Exhibit A

Query Match 99.8%; Score 907.4; DB 14; Length 2045;
Best Local Similarity 99.9%; Pred. No. 3.7e-228;
Matches 908; Conservative 0; Mismatches 1; Indels 0; Gaps 0;

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Qy          1 ATGGCGCTATCCGGGTCGACCCCGGCCCCGTGCTGGGAGGAGGATGAGTGCCTGGACTAC 60
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        121 ATGGCGCTATCCGGGTCGACCCCGGCCCCGTGCTGGGAGGAGGATGAGTGCCTGGACTAC 180

Qy         61 TACGGGATGCTGTCGCTTCACCGTATGTTCGAGGTGGTGGGCGGGCAACTGACCGAGTGC 120
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        181 TACGGGATGCTGTCGCTTCACCGTATGTTCGAGGTGGTGGGCGGGCAACTGACCGAGTGC 240

Qy        121 GAGCTGGAGCTCCTGGCCTTTCTGCTGGATGAGGCTCCTGGCGCCGCCGGAGGCTTAGCC 180
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        241 GAGCTGGAGCTCCTGGCCTTTCTGCTGGATGAGGCTCCTGGCGCCGCCGGAGGCTTAGCC 300

Qy        181 CGGGCCCGCAGCGGCCTAGAGCTCCTGCTGGAGCTGGAGCGCCGCGGGCAGTGCGGCGAG 240
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        301 CGGGCCCGCAGCGGCCTAGAGCTCCTGCTGGAGCTGGAGCGCCGCGGGCAGTGCGACGAG 360

Qy        241 AGCAACCTGCGGCTGCTGGGGCAACTCCTGCGCGTGCTGGCCCGCCACGACCTGCTGCCG 300
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        361 AGCAACCTGCGGCTGCTGGGGCAACTCCTGCGCGTGCTGGCCCGCCACGACCTGCTGCCG 420

Qy        301 CACCTGGCGCGCAAGCGGCGCCGGCCAGTGTCTCCAGAACGCTATAGCTATGGCACCTCC 360
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Db        421 CACCTGGCGCGCAAGCGGCGCCGGCCAGTGTCTCCAGAACGCTATAGCTATGGCACCTCC 480

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Qy        601 CGGGTTCGAGCAGAGTACTGCGAGCATGGGCCAGCCTTGGAGCAGGGCGTGGCATCCCGG 660
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Qy        841 ACTGAGGCCCTGCGAGAGGCTGTGGGCCGGGAGGCTGTTCGCCTGCTGGTCAGTGTGGAT 900
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RESULT 4
US-10-106-698-349
; Sequence 349, Application US/10106698
; Publication No. US20030109690A1
; GENERAL INFORMATION:
; APPLICANT: Ruben et al.
; TITLE OF INVENTION: Colon and Colon Cancer Associated Polynucleotides and Polypepti
; FILE REFERENCE: PA005P1
; CURRENT APPLICATION NUMBER: US/10/106,698
; CURRENT FILING DATE: 2002-03-27
; PRIOR APPLICATION NUMBER: PCT/US00/26524
; PRIOR FILING DATE: 2000-09-28
; PRIOR APPLICATION NUMBER: US 60/157,137
; PRIOR FILING DATE: 1999-09-29
; PRIOR APPLICATION NUMBER: US 60/163,280
; PRIOR FILING DATE: 1999-11-03
; NUMBER OF SEQ ID NOS: 8564
; SOFTWARE: PatentIn Ver. 3.0
; SEQ ID NO 349
; LENGTH: 2045
; TYPE: DNA
; ORGANISM: Homo sapiens
US-10-106-698-349

E

Query Match 99.8%; Score 907.4; DB 15; Length 2045;
Best Local Similarity 99.9%; Pred. No. 3.7e-228;

GenCore version 5.1.6

OM nucleic - nucleic search, using sw model

Run on: March 23, 2005, 09:53:17 ; Search time 1167.43 Seconds
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Scoring table: IDENTITY_NUC
Gapop 10.0 , Gapext 1.0

Searched: 5552208 seqs, 2979665951 residues

Total number of hits satisfying chosen parameters: 11104416

Minimum DB seq length: 0
Maximum DB seq length: 2000000000

Post-processing: Minimum Match 0%
Maximum Match 100%
Listing first 45 summaries

Database : Published_Applications_NA:*
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Pred. No. is the number of results predicted by chance to have a score greater than or equal to the score of the result being printed, and is derived by analysis of the total score distribution.

SUMMARIES

Result No.	Score	% Query Match	Length	DB	ID	Description
1	1787.2	94.9	2045	14	US-10-013-477-2	Sequence 2, Appli
2	1787.2	94.9	2045	15	US-10-106-698-349	Sequence 349, App
3	1775.2	94.3	2044	9	US-09-925-302-315	Sequence 315, App
4	1775.2	94.3	2044	10	US-09-925-302-315	Sequence 315, App
5	1681.4	89.3	1924	14	US-10-001-254-17	Sequence 17, Appl
6	1630.4	86.6	1966	9	US-09-822-830A-390	Sequence 390, App
7	1339	71.1	1570	17	US-10-296-115-481	Sequence 481, App
8	1319.6	70.1	1554	9	US-09-799-777-103	Sequence 103, App
9	1180.8	62.7	1230	16	US-10-296-539-4	Sequence 4, Appli
10	719	38.2	847	17	US-10-641-643-182	Sequence 182, App
11	628	33.4	1067	15	US-10-037-270-853	Sequence 853, App
12	628	33.4	1067	17	US-10-117-722-853	Sequence 853, App
13	513.8	27.3	523	9	US-09-796-692-2721	Sequence 2721, Ap
14	513.8	27.3	523	14	US-10-040-862-2721	Sequence 2721, Ap
15	513.8	27.3	523	17	US-10-057-475B-2721	Sequence 2721, Ap
16	513.8	27.3	523	17	US-10-154-884B-2721	Sequence 2721, Ap
17	513.8	27.3	523	18	US-10-764-324-2721	Sequence 2721, Ap
c 18	365.6	19.4	111084	18	US-10-723-860-1627	Sequence 1627, Ap
19	302.8	16.1	451	10	US-09-918-995-28421	Sequence 28421, A
20	302.8	16.1	484	10	US-09-918-995-12268	Sequence 12268, A
21	301.4	16.0	303	14	US-10-001-254-7	Sequence 7, Appli
22	296.8	15.8	441	9	US-09-867-701-3069	Sequence 3069, Ap
23	206.2	11.0	1142	9	US-09-733-167-2	Sequence 2, Appli
24	206.2	11.0	2261	9	US-09-920-300A-1684	Sequence 1684, Ap
25	206.2	11.0	2261	13	US-10-033-528-1684	Sequence 1684, Ap
26	206.2	11.0	2261	16	US-10-099-926-1684	Sequence 1684, Ap
27	204.6	10.9	1045	9	US-09-935-223-3	Sequence 3, Appli
28	204.6	10.9	2079	18	US-10-357-930-24750	Sequence 24750, A
29	201.2	10.7	1142	9	US-09-733-167-4	Sequence 4, Appli
30	201.2	10.7	1200	9	US-09-935-223-5	Sequence 5, Appli
31	156.4	8.3	630	9	US-09-733-167-8	Sequence 8, Appli
32	122.2	6.5	553	10	US-09-918-995-10904	Sequence 10904, A
33	120.6	6.4	278	14	US-10-066-543-17	Sequence 17, Appl
34	106.2	5.6	180	18	US-10-425-115-111108	Sequence 111108,
35	105.4	5.6	1107	9	US-09-795-651-104	Sequence 104, App
36	88.4	4.7	342	9	US-09-733-167-7	Sequence 7, Appli
37	58.4	3.1	1036	14	US-10-123-155-142	Sequence 142, App
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39	58.4	3.1	1036	15	US-10-140-472-142	Sequence 142, App
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42	58.4	3.1	1036	16	US-10-158-790-142	Sequence 142, App
43	58.4	3.1	1036	17	US-10-137-871-142	Sequence 142, App
44	58.4	3.1	1036	17	US-10-140-923-142	Sequence 142, App
45	58.4	3.1	1036	17	US-10-141-756-142	Sequence 142, App

ALIGNMENTS

RESULT 1
US-10-013-477-2
; Sequence 2, Application US/10013477
; Publication No. US20030049732A1
; GENERAL INFORMATION:
; APPLICANT: Ni et al.
; TITLE OF INVENTION: Apoptosis Related Polynucleotides, Polypeptides, and Antibodies
; FILE REFERENCE: PT002P1
; CURRENT APPLICATION NUMBER: US/10/013,477
; CURRENT FILING DATE: 2001-12-13
; PRIOR APPLICATION NUMBER: 09/669,445
; PRIOR FILING DATE: 2000-09-25
; PRIOR APPLICATION NUMBER: PCT/US00/06642
; PRIOR FILING DATE: 2000-03-15
; PRIOR APPLICATION NUMBER: 60/126,018
; PRIOR FILING DATE: 1999-03-24
; PRIOR APPLICATION NUMBER: 60/139,638
; PRIOR FILING DATE: 1999-06-17
; PRIOR APPLICATION NUMBER: 60/149,449
; PRIOR FILING DATE: 1999-08-18
; NUMBER OF SEQ ID NOS: 27
; SOFTWARE: PatentIn Ver. 2.0
; SEQ ID NO 2
; LENGTH: 2045
; TYPE: DNA
; ORGANISM: Homo sapiens
US-10-013-477-2

Exhibit B

Query Match 94.9%; Score 1787.2; DB 14; Length 2045;
Best Local Similarity 96.8%; Pred. No. 0;
Matches 1858; Conservative 0; Mismatches 3; Indels 59; Gaps 1;

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Qy       143 CCCCGGCCCCGTGCTGGGAGGAGGATGAGTGCCTGGACTACTACGGGATGCTGTCGCTTC 202
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Qy       203 ACCGTATGTTCGAGGTGGTGGGCGGGCAACTGACCGAGTGCGAGCTGGAGCTCCTGGCCT 262
Db       200 ACCGTATGTTCGAGGTGGTGGGCGGGCAACTGACCGAGTGCGAGCTGGAGCTCCTGGCCT 259
Qy       263 TTCTGCTGGATGAGGCTCCTGGCGCCGCCGGAGGCTTAGCCCGGGCCCGCAGCGGCCTAG 322
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Qy       383 GGCAACTCCTGCGCGTGCTGGCCCGCCACGACCTGCTGCCGCACCTGGCGCGCAAGCGGC 442
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Qy       443 GCCGGCCAGTGTCTCCAGAACGCTATAGCTATGGCACCTCCAGCTCTTCAAAGAGGACAG 502
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Qy       563 GGGAGACAGGCTCCCCCCCCAACCAAGCGGCAGCGGCGGAGTCGGGGCCGGCCCAGTGGTG 622
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US-10-106-698-349
; Sequence 349, Application US/10106698
; Publication No. US20030109690A1
; GENERAL INFORMATION:
; APPLICANT: Ruben et al.
; TITLE OF INVENTION: Colon and Colon Cancer Associated Polynucleotides and Polypeptide
; FILE REFERENCE: PA005P1
; CURRENT APPLICATION NUMBER: US/10/106,698
; CURRENT FILING DATE: 2002-03-27
; PRIOR APPLICATION NUMBER: PCT/US00/26524
; PRIOR FILING DATE: 2000-09-28
; PRIOR APPLICATION NUMBER: US 60/157,137
; PRIOR FILING DATE: 1999-09-29
; PRIOR APPLICATION NUMBER: US 60/163,280
; PRIOR FILING DATE: 1999-11-03
; NUMBER OF SEQ ID NOS: 8564
; SOFTWARE: PatentIn Ver. 3.0
; SEQ ID NO 349

; LENGTH: 2045
; TYPE: DNA
; ORGANISM: Homo sapiens
US-10-106-698-349

Query Match 94.9%; Score 1787.2; DB 15; Length 2045;
Best Local Similarity 96.8%; Pred. No. 0;
Matches 1858; Conservative 0; Mismatches 3; Indels 59; Gaps 1;

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Db        80 CTGGCCGGGTTCTGAGCTTGTTCCGCCTCCCTCCCCCGGGAATGGCGCTATCCGGGTCGA 139

Qy       143 CCCCGGCCCCGTGCTGGGAGGAGGATGAGTGCCTGGACTACTACGGGATGCTGTCGCTTC 202
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Qy       443 GCCGGCCAGTGTCTCCAGAACGCTATAGCTATGGCACCTCCAGCTCTTCAAAGAGGACAG 502
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Qy       563 GGGAGACAGGCTCCCCCCCAACCAAGCGGCAGCGGCGGAGTCGGGGCCGGCCCAGTGGTG 622
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Qy       623 GTGCCAGACGGCGGCGGAGAGGGGCCCCAGCCGCACCCCAGCAGCAGTCAGAGCCCGCCA 682
Db       620 GTGCCAGACGGCGGCGGAGAGGGGCCCCAGCCGCACCCCAGCAGCAGTCAGAGCCCGCCA 679

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Qy       803 GGCAGCTGGACGTGTTTGGGCAGGCCACCGCAGTGCTGCGCTCAAGGGACCTGGGCTCTG 862
Db       800 GGCAGCTGGACGTGTTTGGGCAGGCCACCGCAGTGCTGCGCTCAAGGGACCTGGGCTCTG 859

Qy       863 TGGTTTGTGACATCAAGTTCTCAGAGCTCTCCTATCTGGACGCCTTCTGGGGCGACTACC 922
Db       860 TGGTTTGTGACATCAAGTTCTCAGAGCTCTCCTATCTGGACGCCTTCTGGGGCGACTACC 919

Qy       923 TGAGTGGCGCCCTGCTGCAGGCCCTGCGGGGCGTGTTCCTGACTGAGGCCCTGCGAGAGG 982
Db       920 TGAGTGGCGCCCTGCTGCAGGCCCTGCGGGGCGTGTTCCTGACTGAGGCCCTGCGAGAGG 979

Qy       983 CTGTGGGCCGGGAGGCTGTTCGCCTGCTGGTCAGTGTGGATGAGGCTGACTATGAGGCTG 1042
Db       980 CTGTGGGCCGGGAGGCTGTTCGCCTGCTGGTCAGTGTGGATGAGGCTGACTATGAGGCTG 1039

Qy      1043 GCCGGCGCCGCCTGTTGCTGATGGAGGAGGAAGGGGGGCGGCGCCCGACAGAGGCCTCCT 1102
Db      1040 GCCGGCGCCGCCTGTTGCTGATGGAGGAGGAAGGGGGGCGGCGCCCGACAGAGGCCTCCT 1099

Qy      1103 GATCCAGGACTGGCAGGATTGATCCCACCTCCAAGTCTCCGGGCCACCTTCTCCTGGGAG 1162
Db      1100 GATCCAGGACTGGCAGGATTGATCCCACCTCCAAGTCTCCGGGCCACCTTCTCCTGGGAG 1159

Qy      1163 GACGACCATCTCTA---------------------------------------------- 1176
Db      1160 GACGACCATCTCTACCCCTAGAGGACTGTCACTCTAGCATCTTTGAGGACTGCGACAGGA 1219

Qy      1177 ------------CCCCTTGACAGCCCCTCCCACAGGATGTGGGCTCTGAGGCCTAAACC 1223
Db      1220 CCGGGACAGCAGGCCCCTTGACAGCCCCTCCCACAGGATGTGGGCTCTGAGGCCTAAACC 1279

Qy      1224 ATTTCCAGCTGAGTTTCCTTCCCAGACTCCTCCTACCCCCAGGTGTGCCCCCTTAGCCTC 1283
Db      1280 ATTTCCAGCTGAGTTTCCTTCCCAGACTCCTCCTACCCCCAGGTGTGCCCCCTTAGCCTC 1339

Qy      1284 CGGAGGCGGGGGCTGGGCCTGTATCTCAGAAGGGAGGGGCACAGCTACACACTCACCAAA 1343
Db      1340 CGGAGGCGGGGGCTGGGCCTGTATCTCAGAAGGGAGGGGCACAGCTACACACTCACCAAA 1399

Qy      1344 GGCCCCCCTGCACATTGTATCTCTGATCTTGGGCTGTCTGCACTGTCACAGGTGCACACA 1403
Db      1400 GGCCCCCCTGCACATTGTATCTCTGATCTTGGGCTGTCTGCACTGTCACAGGTGCACACA 1459

Qy      1404 CTCGCTCATGCTCACACTGCCCCTGCTGAGATCTTCCCTGGGCCTCTGCCCTGGCCTGCT 1463
Db      1460 CTCGCTCATGCTCACACTGCCCCTGCTGAGATCTTCCCTGGGCCTCTGCCCTGGCCTGCT 1519

Qy      1464 TCCCAGCACACACTTCTTTGGCCTAAGGGCTTCTCTCTCAGGACCTCTAATTTGACCACA 1523
Db      1520 TCCCAGCACACACTTCTTTGGCCTAAGGGCTTCTCTCTCAGGACCTCTAATTTGACCACA 1579

Qy      1524 ACCAACCTGGGCTTCAGCCACATCAGTGGGCACTGGAGCTGGGGTGCACATGGGGCCTGC 1583
Db      1580 ACCAACCTGGGCTTCAGCCACATCAGTGGGCACTGGAGCTGGGGTGCACATGGGGCCTGC 1639

Qy      1584 TCACCTTGCCCACACATCTCCAGCCAGCCAGGGCCCTGCCCAGCTTCAATTTACAGACCT 1643
Db      1640 TCACCTTGCCCACACATCTCCAGCCAGCCAGGGCCCTGCCCAGCTTCAATTTACAGACCT 1699

Qy      1644 GACTCTCCTCACCTTCCCCCCTGCTGTCCAGAGCTGAACATAGACTTGCACTTGGATGTC 1703
Db      1700 GACTCTCCTCACCTTCCCCCCTGCTGTCCAGAGCTGAACATAGACTTGCACTTGGATGTC 1759

Qy      1704 ACCTGGAGTGTCACATGGGAGTGTTATGGCAGCATCATACCAAGGCCTACTGTTGCACAT 1763
Db      1760 ACCTGGAGTGTCACATGGGAGTGTTATGGCAGCATCATACCAAGGCCTACTGTTGCACAT 1819

Qy      1764 GGGGCCAAAACCAGTAAACAGCCACCTTCTTGGAAAGGGAATGCAAAGGCTTTGGGGGTG 1823
Db      1820 GGGGCCAAAACCAGTAAACAGCCACCTTCTTGGAAAGGGAATGCAAAGGCTTTGGGGGTG 1879

Qy      1824 ATGGAAAAGACCTTTTACAAATGATACCAATTAAACTGCCCTGGAAAGGGCATAGGTGGG 1883
Db      1880 ATGGAAAAGACCTTTAACAAATGATACCAATTAAACTGCCCTGGAAAGGGCATAGGTGGG 1939
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RESULT 3
US-09-925-302-315
; Sequence 315, Application US/09925302
; Patent No. US20020044941A1
; GENERAL INFORMATION:
; APPLICANT: Rosen et al.
; TITLE OF INVENTION: Nucleic Acids, Proteins and Antibodies
; FILE REFERENCE: PA104